

## **II. REMARKS**

Claims 26 to 37 are pending.

### **A. Regarding the claim amendments.**

Claims 26 and 32 have been amended to more clearly indicate that the recited heparanase protein can be a fragment of SEQ ID NO:2 or its variant and has endoglycosidase activity.

As discussed in the prior response, U.S. Pat. No. 5,968,822 (hereinafter the '822 patent) issued from U.S. App. Ser. No. 08/922,170, from which the subject application is a continuation-in-part. See page 1, lines 18-21 of subject application. More specifically, Figure 1 and column 7, lines 53-61 of the '822 patent disclose that in SEQ ID NO:2 of the subject application (SEQ ID NO:10 in the '822 patent) the tyrosine residue (which can also be designated "Tyr" or "Y") at position 246 can be substituted with a phenylalanine residue (which can also be designated "Phe" or "F"). The '822 patent further discloses that the protein of the invention includes a functional part or fragment of this sequence that has "heparanase catalytic activity." See, for example, column 12, lines 31-35 of the '822 patent. The term "heparanase catalytic activity" is defined as endoglycosidase hydrolyzing activity. See column 11, lines 50-56.

Similarly, claims 31 and 37 have been amended to more clearly indicate that the recited protein has such endoglycosidase hydrolyzing activity. Support for this amendment can be found, for example, from the same sources discussed above.

In addition, claims 26 and 32 have been amended to more clearly indicate that the claimed antibody can recognize the recited protein. The amendment is supported in the specification, for example, at page 12, lines 10-16, which disclose such recognition.

Because the claim amendments made herein are fully supported by the subject application, including its related applications, no issue of new matter is raised.

**B. Regarding the written description rejection.**

Claims 26 to 37 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

More specifically, the Final Office Action alleges that the claims include proteins that possess 1) “some” activity that may or may not be endoglycosidase hydrolyzing activity; or 2) an “undisclosed” sequence (with deletions, additions or substitutions). In response to these allegations, the pending claims have been amended to more clearly indicate that the recited protein is SEQ ID NO:2, the variant sequence or a fragment of one of these sequences that also has endoglycosidase hydrolyzing activity.

In addition, the Action claims the recited epitope may not necessarily be specific to heparanase. In response, the claims have been amended to more clearly indicate that the claimed antibody recognizes the recited protein. Therefore, this amendment makes clear that the recited epitope is specific to heparanase.

Thus, as amended, the pending claims meet the written description requirement. The skilled artisan can visualize members of this genus. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**C. Regarding the enablement rejection.**

Claims 26 to 37 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. Applicants respectfully traverse this rejection.

More specifically, the Final Office Action alleges that the claims include proteins that possess 1) “some” activity that may or may not be endoglycosidase hydrolyzing activity; or 2) an “undisclosed” sequence (with deletions, additions or substitutions). In response to these allegations, the pending claims have been amended to more clearly indicate that the recited protein is SEQ ID NO:2, the variant sequence or a fragment of one of these sequences that also has endoglycosidase hydrolyzing activity.

In addition, the Action claims the recited epitope may not necessarily be specific to heparanase. In response, the claims have been amended to more clearly indicate that the claimed antibody recognizes the recited protein. Therefore, this amendment makes clear that the recited epitope is specific to heparanase.

Thus, as amended, the pending claims are enabled. The skilled artisan can visualize members of this genus. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**D. Regarding the double patenting rejections.**

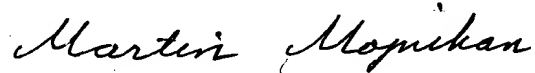
The pending claims are rejected under the judicial doctrine of obviousness-type double patenting over: a) U.S. Pat. No. 6,562,950 B2 in view of other references of record; b) U.S. Pat. No. 6,177,545 B1 in view of other references of record; and c) U.S. App. No. 10/645,659 in view of other references of record. Applicants respectfully traverse these rejections.

Enclosed herewith is a terminal disclaimer disclaiming the period of a patent issuing from the subject application that extends beyond the terms of the above-cited patents or application. Accordingly, withdrawal of these rejections is respectfully requested.

### III. CONCLUSION

All of the issues raised in the Final Office Action have been addressed and are believed to have been overcome. Accordingly, it is respectfully submitted that all the claims under examination in the subject application are allowable. Therefore Applicants respectfully request a Notice of Allowance to this effect.

Respectfully submitted,

A handwritten signature in black ink, reading "Martin Moynihan". The signature is written in a cursive, flowing style.

Martin Moynihan  
Registration No. 40,338

Date: September 28, 2005

Encl.:

Request for Continued examination (RCE)

Extension of Time

Terminal Disclaimer